

AUG 4 2000

**510(k) Summary  
Ceralas Diode Laser System**

K 001475

**Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared**

CeramOptec, Inc.  
515 Shaker Road  
East Longmeadow, Massachusetts 01028  
Phone: (413) 525-0600  
Facsimile: (413) 525-0611

Contact Person: Carol J. Morello, V.M.D.  
Date prepared: June 27, 2000

**Name of Device and Name/Address of Sponsor**

Ceralas Diode Laser System (Model D10-60)  
CeramOptec, Inc.  
515 Shaker Road  
East Longmeadow, MA 01028

**Classification Name**

Surgical laser

**Predicate Device**

Lifestream Int'l Diomed 15,30,60 Surgical Diode Laser  
CeramOptec Ceralas D10 810nm Diode Laser

**Intended Use**

The Ceralas D10-60 has the same intended uses as the predicate device.  
Ear, Nose and Throat and Oral Surgery

Hemostasis, incision, excision, ablation, coagulation, and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity. Examples include

- Removal of benign lesions from the ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in situ
- Ablation and vaporization of hyperkeratosis

- Excision of carcinoma of the larynx
- Laryngeal papillomectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

#### Arthroscopy:

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery. Examples include:

- Meniscectomy
- Synovectomy
- Chondromalacia

#### Gastroenterology

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue in the upper and lower gastrointestinal tracts and also with endoscopic procedures. Examples include:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

#### General Surgery, Dermatology, Plastic Surgery and Podiatry

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion. Examples include:

- Matrixectomy
- Excision of euromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of keloids
- Liver resection
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcers
- Hepatobiliary tumors
- Mastectomy
- Dermabrasion
- Vaporization and hemostasis of capillary hemangioma

- Excision, vaporization and hemostasis of abdominal tumors
- Excision, vaporization and hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorraphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs
- Debridement of wounds
- Photocoagulation of teleangiectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities

### Urology

Excision, vaporization, incision, coagulation, ablation and hemostasis of urological tissues.  
Examples include:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia

### Gynecology

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue.  
Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial neoplasia
- Cervical conization
- Menorrhagia

### Neurosurgery

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Example includes:

- Hemostasis in conjunction with meningiomas

## **Ophthalmology**

**Retinal photocoagulation**

**Diabetic retinopathy**

## **Pulmonary Surgery**

**Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:**

- **Tracheobronchial malignancy or stricture**
- **Benign and malignant pulmonary obstruction**
- **Endoscopic pulmonary applications**

**The Cerals D10-60 Diode Laser operates with a power range of 1-60W in the CW or pulsed mode. The delivery systems for the Ceralas D10-60 Laser System consist of optical fiber fitted with an SMA 905 connector at the proximal end.**

**There are no technological differences between the Ceralas D10-60 Laser System and the Lifestream Int'l Diomed 15,30,60 Surgical Diode Laser System. The Ceralas D10-60 Laser System's principles of operation, function and intended use are similar to the predicate device so no new questions of safety or effectiveness are raised.**

## **Performance Data**

**None required.**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 4 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Carol J. Morello, VMD  
Regulatory Affairs  
CeramOptec, Inc.  
515 Shaker Road  
East Longmeadow, Massachusetts 01028

Re: K001975  
Trade Name: Ceralas D10-60 810nm Diode Laser  
Regulatory Class: II  
Product Code: GEX  
Dated: June 27, 2000  
Received: June 29, 2000

Dear Dr. Morelo:

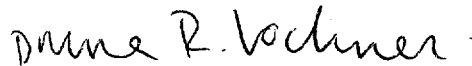
We have reviewed your Section 510(k) notification of intent to market ~~the device referenced~~ above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities ~~under the~~ Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



 Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K001975

Device Name: Ceralas D10-60 810nm Diode Laser

Indications For Use:

See attached listing of indications for use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE).

Dan R. Wachner.  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K001975

(Optional Format 3-10-98)

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- Liver resection
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- Appendectomy
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- Excision, vaporization and hemostasis of abdominal tumors
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### Neurosurgery

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Example includes:

- Hemostasis in conjunction with meningiomas

### Ophthalmology

Retinal photocoagulation

Diabetic retinopathy

### Pulmonary Surgery

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:

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- Benign and malignant pulmonary obstruction
- Endoscopic pulmonary applications